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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,298	04/07/2004	John Sefton	17224CON (AP)	7456

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
03/07/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents_ip@allergan.com

Office Action Summary	Application No.	Applicant(s)	
	10/820,298	SEFTON, JOHN	
	Examiner	Art Unit	
	Barbara P. Badio	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6 and 11-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 1, 6 and 11-13 are pending in the present application. The instant claims stand rejected as indicted below.

Specification

3. Applicant continues to argue that all trademarks are capitalized with generic terminology provided and requests identification of incorrectly identified trademarks. The examiner points to page 3, lines 19-20; page 3, line 23 - page 4, line 2 and page 13, lines 16-17.

Claim Rejections - 35 USC § 112

4. Claims 1, 6 and 11-13 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims recite a gel comprising about 0.01% to about 2% **w/v**. However, the present specification sets forth

percentages by **w/w** (see page 5, lines 15-23). There is no mention of percentages by **w/v** in the present specification. Applicant's attention is directed to MPEP § 706.03(o). It is suggested that "**w/v**" be rewritten as "**w/w**" as set forth by the present specification.

Double Patenting

5. The rejection of claims 1, 6 and 11-13 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,974,807 is maintained.

Applicant argues the claims as amended are not obvious over the claims of US Patent No. 6,974,807. Applicant's argument was considered but not persuasive for the following reason.

Unlike the claims of the cited patent, the claims as amended recite specific combination of excipients. However, said combination is rendered obvious by the disclosure of the cited patent (see col. 4, lines 15-33 of the cited patent). It is noted by MPEP § 804, IIB(I), that those portions of the specification that provide support for the patent claims may be examined and considered when addressing the issue of whether a claim defines an obvious variation of an invention claimed in the patent.

For this reason and those given in the previous Office Actions, the rejection of claims 1, 6 and 11-13 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,974,807 is maintained.

Claim Rejections - 35 USC § 103

6. The rejection of claims 1, 6 and 11-13 under 35 USC 103(a) over Yamamoto (US 5,236,906) or Shimizu et al. (US 6,248,779) and Nagpal et al. (US 5,650,279) is withdrawn.

7. The rejection of claims 1, 6 and 11-13 under 35 USC 103(a) over Smith (US 5,874,074) or Sequeira et al. (US 4,775,529) and Nagpal et al. (US 5,650,279) is withdrawn.

8. Claims 1, 6 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto (US 5,236,906), Shimizu et al. (US 6,248,779), Nagpal et al. (US 5,650,279) and Charu (US 5,914,334) in combination.

Each of Yamamoto and Shimizu et al. teaches the use of adrenocortical hormones, such as betamethasone valerate and/or alclometasone dipropionate, in the treatment of dermatoses such as atopic dermatitis and/or psoriasis (see **'906**, col. 1, line 11 - col. 2, line 55; **'779**, col. 1, lines 10-18; col. 2, lines 20-29; col. 6, lines 40-65).

Nagpal et al. teaches it is known in the art to use tazarotene in the treatment of psoriasis and exemplifies the use of a 0.05% cream (see col. 1, lines 42-47; Example 9).

Charu teaches a stable gel formulation for topical treatment of skin conditions such as psoriasis and acne comprising tazarotene in a pharmaceutical carrier comprising water, edentate disodium, ascorbic acid, carbomer 934P, poloxamer 407,

polyethylene glycol, polysorbate 40, hexylene glycol, butylated hydroxytoluene, butylated hydroxyanisole, benzyl alcohol and tromethamine and exemplifies several compositions comprising 0.1, 0.05 and 0.025 w/w of tazarotene (see the entire article, especially col. 2, lines 24-50; Table II; col. 5, Table III; col. 9, lines 45-50).

The instant claims differ from the cited references by reciting the treatment of proliferative skin diseases by the administration of an effective amount of about 0.01% to about 2% tazarotene gel and an effective amount of a corticosteroid, i.e., alclometasone dipropionate and/or betamethasone valerate.

As recognized by MPEP § 2144.06(I):

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.), and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious).

Thus, the combination of the compounds taught by Yamamoto/Shimizu and Nagpal/Charu for the treatment of dermatoses to a patient in need of said treatment would have been prima facie obvious to the skilled artisan in the art at the time of the present invention. As noted above, the idea to combine flows logically from their having

been individually taught in the prior art for treatment of dermatoses, including psoriasis and atopic dermatitis, i.e., the same disorder(s).

Claim 11 further differs from the cited references by reciting the administration of tazarotene once daily in the evening and the corticosteroid once daily in the morning. However, the medical art teaches combination therapy as well as administration of the drugs involve in combination therapy at different times during the day. In addition, absence a showing of criticality of the order and/or time of administration of the drugs in a combination therapy, said recitation is not considered a patentable limitation.

9. Claims 1, 6 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 5,874,074), Sequeira et al. (US 4,775,529), Nagpal et al. (US 5,650,279) and Charu (US 5,914,334) in combination.

Each of Smith and Sequeira et al. teaches the use of corticosteroids, such as betamethasone dipropionate, mometasone furoate and/or alclometasone dipropionate in the treatment of psoriasis (see **'074**, col. 4, lines 47-67; **'529**, col. 1, lines 36-63).

Nagpal et al. teaches it is known in the art to use tazarotene in the treatment of psoriasis and exemplifies the use of a 0.05% cream (see col. 1, lines 42-47; Example 9).

Charu teaches a stable gel formulation for topical treatment of skin conditions such as psoriasis and acne comprising tazarotene in a pharmaceutical carrier comprising water, edentate disodium, ascorbic acid, carbomer 934P, poloxamer 407, polyethylene glycol, polysorbate 40, hexylene glycol, butylated hydroxytoluene,

butylated hydroxyanisole, benzyl alcohol and tromethamine and exemplifies several compositions comprising 0.1, 0.05 and 0.025 w/w of tazarotene (see the entire article, especially col. 2, lines 24-50; Table II; col. 5, Table III; col. 9, lines 45-50).

The instant claims differ from the cited references by reciting the treatment of proliferative skin diseases by the administration of an effective amount of about 0.01% to about 2% tazarotene gel and an effective amount of a corticosteroid, i.e., alclometasone dipropionate and/or betamethasone valerate.

As recognized by MPEP § 2144.06(I):

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious).

Thus, the combination of the compounds taught by Smith/Sequeira and Nagpal/Charu for the treatment of dermatoses to a patient in need of said treatment would have been prima facie obvious to the skilled artisan in the art at the time of the present invention. As noted above, the idea to combine flows logically from their having

been individually taught in the prior art for treatment of dermatoses, including psoriasis and atopic dermatitis, i.e., the same disorder(s).

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Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1628